Subpart A—General Provisions

§ 433.1 Exemption of antibiotic drugs for human use from batch certification requirements.

(a) Antibiotic drugs for human use are exempt from the batch certification requirements of part 431 of this chapter if the conditions of paragraph (b) of this section are met; or, in the case of over-the-counter antibiotic drugs subject to an over-the-counter drug monograph in this chapter, if the conditions of paragraph (c) of this section are met.

(b) The conditions are as follows:

(1) The antibiotic drug is approved for marketing under an appropriate antibiotic application or abbreviated antibiotic application or is the subject of review under the Drug Efficacy Study Implementation Program.

(2) The antibiotic drug is packaged and labeled for dispensing in accordance with the applicable regulation (monograph) in this chapter except where other labeling has been approved in an applicable antibiotic application or abbreviated antibiotic application.

(3) The bulk antibiotic drug used in preparing the antibiotic drug product meets the standards of identity, strength, quality, and purity specified in the applicable regulation (monograph) in this chapter except where other standards have been approved in an applicable antibiotic application or abbreviated antibiotic application.

(4) The antibiotic drug product meets the standards of identity, strength, quality, and purity specified in the applicable regulation (monograph) in this chapter except where other standards have been approved in an applicable antibiotic application or abbreviated antibiotic application.

(c) The over-the-counter antibiotic drug product for human use is required to meet the general conditions established in § 330.1 of this chapter, and the conditions specified in an applicable over-the-counter drug monograph in this chapter.

(d) In accordance with the provisions of section 507(e) of the act, an antibiotic-containing drug for human use exempt from the requirements for batch certification under paragraph (b) of this section is subject following its approval to section 505 of the act and applicable regulations for new drugs, generally parts 310 through 314 of this chapter. For each antibiotic drug subject to an exemption under paragraph (b) of this section:

(1) An approved antibiotic application is regarded to be an approved application under § 314.50 of this chapter.

(2) An approved abbreviated antibiotic application is regarded to be an approved abbreviated application under § 314.94 of this chapter.

(e) Nothing in this section prevents a manufacturer from applying for batch certification of an antibiotic drug for human use subject to an exemption under this section as provided in section 507(c) of this act.

(f) All exemptions from batch certification requirements for antibiotic drugs for human use under this section are subject to the conditions of effectiveness under § 433.2.

(Approved by the Office of Management and Budget under control number 0910–0001)

[51 FR 25524, July 15, 1986; 51 FR 30478, Aug. 27, 1986, as amended at 57 FR 18001, Apr. 28, 1992]

§ 433.2 Conditions on the effectiveness of exemptions of antibiotic drugs for human use from batch certification requirements.

(a) If at any time an exemption from batch certification requirements for an antibiotic drug for human use has been granted, the Commissioner finds on the basis of new information before the agency with respect to such exempted drug, evaluated together with the evidence available to the agency when such exemption was granted, that certification of each batch is necessary to ensure its safety and efficacy of use, the Commissioner shall act immediately to revoke all exemptions from batch certification requirements granted for such drug.

(b) If the Commissioner finds that the person granted an exemption from batch certification requirements for an antibiotic drug for human use has failed either to comply with the requirements of section 505 of the act and the regulations promulgated thereunder or to meet the general conditions established in § 330.1 of this chapter and the conditions specified in an

applicable over-the-counter drug monograph in this chapter; or if the Commissioner finds that the requirements of §433.1 have not been met; or if the Commissioner finds that the petition for exemption from batch certification contains any false statements of fact, the Commissioner may revoke the exemption from batch certification requirements immediately and require batch certification of the drug until such person shows adequate cause why the exemption from batch certification requirements should be reinstated.

(c) If the Commissioner repeals or suspends an exemption from batch certification requirements for an antibiotic drug for human use, a notice to that effect and the reasons therefor will be published in the FEDERAL REGISTER.

(d) Any person who contests the revocation or suspension or denial of reinstatement of an exemption from batch certification requirements for an antibiotic drug for human use shall have an opportunity for a regulatory hearing before the Food and Drug Administration under part 16 of this chapter.

[47 FR 39159, Sept. 7, 1982, as amended at 51 FR 25524, July 15, 1986]

§433.3 Assay requirements for antibiotic drugs exempted from certification.

(a) Certain antibiotic drugs are exempted by regulations in this chapter from the certification requirements of sections 507 and 512 of the act if such drugs comply with standards prescribed by such regulations and on condition that the label of each package bears an expiration date which is determined from the date during which the batch was last assayed and released by the manufacturer.

(b) It is the position of the Food and Drug Administration that if each batch of such exempted drugs is not tested by the manufacturer or his agent to determine whether it complies with the standards of identity, strength, quality, and purity prescribed for it, the batch is not exempt from certification and it may be deemed to be misbranded under section 502(l) of the act or be adulterated under section 501(a)(5) of the act when in interstate commerce.

Subpart B—Exemptions for Which an Application or Notice Is Required

§433.12 Exemption for labeling.

(a) Except as provided by paragraphs (c) and (d) of this section, a shipment or other delivery of a certifiable antibiotic drug which is to be labeled at an establishment located elsewhere than at the place of manufacture shall be exempt, during the time of introduction into and movement in interstate commerce and the time of holding in such establishment, from the requirement of section 502(l) of the act or the certification requirements of section 512(n) of the act if the labeling of each shipping container bears the batch mark of the drug, the number of units per package and the expiration date, and if the person who introduced such shipment or delivery into interstate commerce holds a permit (Antibiotic Form 3) from the Commissioner authorizing shipment for labeling in such establishment.

(b)(1) An application for such a permit shall be in a form specified by the Commissioner and shall give the name and location of the establishment in which such labeling is to be done.

(2) In case the applicant is the operator of such establishment, the application shall include a written agreement signed by him that he will request certification of each batch from which any shipment or delivery is made to such establishment unless it is exempt under section 801(d) of the act or §433.17; that he will not remove any of such antibiotic drug from such establishment unless it complies with section 502(l) of the act or the certification requirements of section 512(n) of the act or is so exempt, or if certification is refused, unless it is returned within a reasonable time to permit reprocessing and certification, destruction, or such exemption at the establishment where it was manufactured; that he will keep complete records showing the date, quantity, and batch mark of each such shipment and delivery and the disposition thereof; that he will make such records available to any officer or employee of the Food and Drug Administration at any reasonable hour within 3 years after the